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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,314	05/17/2005	David Wallach	WALLACH33	6672

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EXAMINER	
SWOPE, SHERIDAN	

ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,314	WALLACH ET AL.	
	Examiner	Art Unit	
	Sheridan L. Swope	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-25,66-70 and 72-76* is/are pending in the application.

4a) Of the above claim(s) *20-25,68,71 and 72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *66,67,69,70 and 73-76* is/are rejected.

7)☒ Claim(s) *66,67,69,70 and 73-76* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response on October 11, 2007, to the First Action on the Merits of this case mailed April 11, 2007, is acknowledged. It is acknowledged that applicants have cancelled Claim 71, amended Claims 20, 24, 66, 69, 70, and 73, and added Claim 76. Claims 20-25, 66-70, 72-76 are pending. Claims 21, 22, 25, 68, 71 and 72 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 20, 23, and 24 are herein withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicants are reminded that their elected invention is directed to a method for treatment of a disease involving IL-2, rheumatoid arthritis, using the NIK polypeptide of SEQ ID NO: 18. Claims 66, 67, 69, 70, and 73-76 are hereby considered.

Specification-Objections

The specification is objected to because the tables are not numbered in sequence. Some tables are identified with letters, such as "A", while other tables are identified by numbers, such as "1". Identification of the tables should use a consistent format and be in the sequence mentioned in the text of the specification.

Claims-Objections

Objection to the claim set for not beginning with a sentence of which the claims are an object e.g., "We claim" or "The claims are", is maintained (see MPEP 608.01(m)). Applicants may make the appropriate amendment in either the claim set or on a separate page.

Claims 66, 67, 69, 70, and 73-76 are object to for reciting non-elected subject matter.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Rejection of Claims 66, 67, 69, 70, and 73-75 under 35 U.S.C. 112, first paragraph/lack of enablement, for the reasons explained in the prior action, is maintained. New Claim 76 is herein rejected under 35 U.S.C. 112, first paragraph/lack of enablement, for the same reasons.

In support of their request that said rejection be withdrawn, Applicants provide the following arguments.

(A) The claims have been amended such that the scope is now more directly related to the enabling disclosure. For example, the amount of NIK to be administered is an amount effective to bind to cγc and inhibit cγc/NIK interaction. Because functional limitations have been added, the claims no longer read on any variants, only those with the recited function.

(B) The skilled artisan would expect that a variant that binds to cγc and inhibits cγc/NIK interaction would indeed treat a disease that involved signaling of a cytokine via cγc.

These arguments are not found to be persuasive for the following reasons.

(A) Reply: It is acknowledged that the claims have been amended to recite the functional limitation of "administering an amount of a fragment of NIK effective to bind to cγc and inhibit cγc/NIK interaction". However, the claims also recite the use of any mutein, variant, fusion protein, functional derivative, circularly permutated derivative, or fragment of SEQ ID NO: 18 having said function. Thus, the claims fail to provide any structural limitations. Since

the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. Neither the specification nor the prior art provide guidance as to how the structure/sequence of SEQ ID NO: 18 can or cannot be altered and retain the desired activity. It is acknowledged that methods for making variants of SEQ ID NO: 18 and methods of testing peptides for the desired ability to bind to cγc and inhibit cγc/NIK interaction ***in vitro*** are known. However, without sufficient guidance, the skilled artisan is reduced to making and testing the unlimited number of structural variants encompassed by "any mutein, variant, fusion protein, functional derivative, circularly permutated derivative, or fragment of SEQ ID NO: 18". Clearly said making and testing represents undue experimentation. Moreover, the specification has failed to enable the artisan to know the amount of the peptide of SEQ ID NO: 18 that must be administered ***in vivo*** in order to bind to cγc, inhibit cγc/NIK interaction, or treat any cytokine-mediated disorder.

(B) Reply: It is acknowledged that the skilled artisan would expect that a variant of SEQ ID NO: 18 that binds to cγc and inhibits cγc/NIK interaction would indeed treat some diseases that involve signaling of a cytokine via cγc ie, those affected by a cγc/NIK interaction. However, neither the specification nor the art provide evidence (1) that all cytokines act via a cγc/NIK interaction, (2) that all diseases due to improper signaling of a cytokine can be treated by affecting cγc/NIK interaction, (3) for which diseases can be treated by affecting cγc/NIK

interaction, (4) for the amount of peptide needed to delivered *in vivo* to have the desired utility. Thus, the skilled artisan is left with the task of determining which diseases can or cannot be treated by affecting cγc/NIK interaction and how much peptide to be administered. Applicants have merely asserted that any disease that is mediated by a cγc/NIK interaction can be treated by blocking said interaction and left to the public the job of determining the identity of said diseases.

Written Description

Rejection of Claims 66, 67, 69, 70, and 73-75 under 35 U.S.C. 112, first paragraph/insufficient written description, for the reasons explained in the prior action, is maintained. New Claim 76 is herein rejected first paragraph/ insufficient written description, for the same reasons.

In support of their request that said rejection be withdrawn, Applicants provide the following arguments.

(C) The terminology "via any IL-2 cγc" is not understood.

(D) The claims have been amended to recite the functional limitation of "administering an amount of a fragment of NIK effective to bind to cγc and inhibit cγc/NIK interaction.

(E) SEQ ID NO: 18, SEQ ID NO: 19, and AlyNIK are species of the genus of compound to be used in the recited method.

These arguments are not found to be persuasive for the following reasons.

(C) Reply: It is acknowledged that, for each organism, cγc is a specific protein. This basis for the rejection is withdrawn.

(D) Reply: It is acknowledged that the claims have been so amended. However, the claims recite "any mutein, variant, fusion protein, functional derivative, circularly permutated derivative, or fragment of SEQ ID NO: 18"; thus, the claims fail to recite any structural limitation. It is acknowledged that the specification teaches that SEQ ID NO: 18 is the region of NIK responsible for binding to cγc [0216] and the skilled artisan would believe that, more likely than not, the peptide of SEQ ID NO: 18 would be effective at inhibiting cγc/NIK interaction. However, the specification fails to describe any other peptides effective at inhibiting cγc/NIK interaction. Moreover, the specification has failed to describe the amount of the peptide of SEQ ID NO: 18, or any variant thereof, that must be administered ***in vivo*** in order to bind to cγc, inhibit cγc/NIK interaction, or treat any cytokine-mediated disorder. In fact, the specification fails to describe a method of treating/preventing any disorder using the peptide of SEQ ID NO: 18, or any variant thereof.

(E) Reply: See (D) above.

Allowable Subject Matter

No claims are allowable.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Any new references were cited solely to reject amended claims or rebut Applicants' arguments. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.
Art Unit 1652

SHERIDAN SWOPE, PH.D.
PRIMARY EXAMINER